Assembly Committee on Health and Health Care Reform
Assembly Bill 366
Representative Peter Barca
September 30, 2009

Chairman Richards and members of the Assembly Committee on Health and Health Care Reform, thank you for holding a public hearing on Assembly Bill 366.

As we discussed during the floor session earlier this month, we face a deeply troubling issue with drunk driving in our state and we need a comprehensive approach to reduce OWIs including prevention, punishment, supervision and, in many respects most important, treatment.

Treatment, when it is effective, not only reduces drunk driving and protects the driving public, it saves the lives and preserves the well being of Wisconsin families, saves money, makes our workforce more productive, and makes our society stronger.

The social and economic costs as well as the adverse affect on families of alcohol and drug abuse is well documented.

Naltrexone is an innovative, evidence based approach to AODA treatment which will get at the root of repeat drunk drivers and alcoholism. Clinical trials have confirmed its effectiveness in reducing alcohol abuse, lowering relapse rates and improving treatment outcomes. Yet despite strong evidence of naltrexone's effectiveness, it is not a widely available treatment option.

This bill allows 2nd and 3rd OWI offenders to be placed on probation if, as a condition of probation, the court requires the person to take a therapeutically indicated dose of the drug naltrexone or alternative drugs under an amendment I will discuss shortly.

For that reason and others to be discussed, this bill dovetails well with the drunk driving package we passed with the added probation options, parole agents and safe streets program.

If the judge chooses to place a person on probation under these terms, AB 366 allows the same minimum and maximum period of imprisonment for the offense, but the bill eliminates the mandatory minimum fine as a judge may factor in the costs of ordering somewhat costly monthly injections. The court may impose a fine in any amount up to the maximum allowed under current law.

Rep. Roys and I have been working with the Attorney General's office on an amendment to AB 366 which allows the judge to have a broad range of pharmaceutical and non-pharmaceutical AODA treatment options as a condition of probation.

Thank you for your attention today and I hope you can support AB 366 when it faces executive action before your committee.

A. Background Information

- Idea originated from LaFollette Institute presentation to legislators in January on the serious problems involving alcohol abuse in WI & the effectiveness of naltrexone in AODA treatment
- Carolyn Heinrich: Director, LaFollette School of Public Affairs presented the data.
- Dr. Richard Brown: Clinical Director, WI Initiative to Promote Healthy Lifestyles and Associate Professor, Department of Family Medicine at UW School of Medicine and Public Health has worked with Rep. Barca and Rep. Roys on this bill.
- Drug therapy such as Naltrexone is recommended by National Conference on Highway Safety Priorities as an innovative OWI sentence strategy
- Governor Doyle's Subcommittee on Impaired Driving recommended expanding the availability of probation as an option when determining sentencing for repeat offenders. Judicial discretion to individualize sentencing to include supervision along with counseling or treatment could help to rehabilitate the offender and improve road safety

B. Alcohol Abuse is a huge problem in WI:

- According to the WI Initiative to Promote Healthy Lifestyles: WI is at or near the top nationally for high-risk and heavy drinking.
- About 25% of WI adults engage in at-risk or problem drinking or drug use.
- Pregnant women in WI drink more than in the rest of the U.S.
- Injuries and diseases related to drinking and drug use make it the 4th leading cause of death and hospitalization in WI. Drinking is the leading cause of disability among men.
- Direct and indirect costs of alcoholism are about $185 billion annually. On average, states spend about $1 of every $7 of total spending on programs related to substance abuse and its consequences (National Center on Addiction and Substance Abuse 2001).
- WI is rated as the worst state in the nation when it comes to the number of drunk driving fatalities. Currently 42% of our state's car traffic fatalities are caused by drunk drivers.
- Average Blood Alcohol Concentration (BAC) of drunk drivers in WI is .17, more than twice the legal limit of .08.

C. Quick facts about OWI'S

- The average cost of an Operating While Intoxicated (OWI) first offense is approximately $3,000 taking into account the insurance increase for several

years after conviction.

- The average BAC for an OWI in Wisconsin is .17 or approximately eight drinks in a 160 pound person at the time of testing.
- BAC and Risks of an Accident: at .04 the probability of a crash increases significantly and climbs rapidly after .08.
- For drivers at the average BAC of .17 the chances of an accident is increased by 400 times.
- In Wisconsin each year one out of every 141 people will be cited for OWI, approximately 37,000 each year.
- 20% of all fatal accidents are caused by drivers with a BAC of less than .10.
- Of the 37,000 arrests each year, there is a conviction rate of about 92%.
- Most OWI's and OWI deaths occur between the ages of 25 and 34.
- The cost to our nation each year is approximately **$230 billion** in OWI related accidents, injuries, and deaths.

D. Naltrexone is part of a rising generation of anti-addiction drugs that block pleasure from alcohol and opiates:

- Naltrexone is not addictive and it produces no opiate-like effects. Its side effects were few in a large study of alcoholism, mainly a small increase in nausea compared to the placebo group.

- Naltrexone is an opiate inhibitor, it blocks pleasure and reduces cravings for opiates and alcohol which helps users remain abstinent. It doesn't make the user feel sick.

- A extended-release form of naltrexone, approved by the FDA in 2006, can be administered monthly as an injection providing a gradual release and long acting protection from the effects of alcohol or opiates.

- Professionals who work with alcoholics know opiate inhibitors like naltrexone have a solid track record in helping some people curb their addictions. Allowing this treatment as a condition of OWI probation is one more step we can take to reduce repeat drunk driving in Wisconsin.

State of Wisconsin
Department of Health Services

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Assembly Committee on Health & Healthcare Reform
September 30, 2009
Public Hearing on AB 366

Chairman Richards and members of the Committee on Health and Healthcare Reform, thank you for the opportunity to speak with you today. My name is John Easterday. I serve as the Division Administrator for the Division of Mental Health and Substance Abuse Services at the Department of Health Services. I am here today to provide information to the Committee on the use of medication-assisted treatment, which is a component of AB 366.

The Department believes in medication-assisted treatment (MAT) as part of a comprehensive approach in the treatment of dependence and addiction. MAT combines pharmacological intervention with counseling and behavioral therapies and focuses on the patient as an individual and care is provided as such. When MAT is comprehensive, leveraging medication with psychosocial treatment, the results are significantly more successful and treatment outcomes are improved.

Naltrexone is just one of many drugs that are currently utilized to assist alcohol dependent patients. It reduces the desire for alcohol by blocking the parts of the brain that are the pleasure zones and assists in keeping the patient abstinent. Unlike disulfram (Antabuse), naltrexone does not make individuals sick if they consume alcohol while taking the medication and patients report that they are largely unaware of being on the medication. All patients will need follow-up liver functioning tests while taking naltrexone.

A naltrexone candidate is:

- Medically stable
- Willing to take the medication for a minimum of 12 weeks along with the traditional treatment for alcohol dependence
- Alcohol free for five days prior to first dosing
- Opioid free for at least 7-10 days
- Has no active or severe liver or kidney problems and must have periodic liver function tests
- Not allergic to the drug

Naltrexone is contraindicated in:

- Patients with acute liver failure or hepatitis
- Patients on opioid (narcotic) analgesics
- Patients dependent on opioids (including those maintained on opiate agonists such as methadone and buprenorphine)
- Patients in acute opioid withdrawal
- Patients who have positive urine drug screens for other illicit substances
- Sensitive to naltrexone
- In women who are pregnant

I have included answers to frequently asked questions about use of naltrexone from the APT Foundation for the Committee's consideration.

Importantly, medications for alcohol dependence do not replace counseling and adjunctive treatment, which are essential to the overall outcomes of alcohol dependence. Many addictions coincide with other physical or mental health problems, which treatment must take into consideration. Without a complete evaluation and assessment, even an individual arrested for operating while intoxicated (OWI) cannot be considered alcohol dependent. Naltrexone should be part of a comprehensive treatment and recovery program that includes psychosocial support and participating in 12-Step or other mutual support group programs.

The use of MAT is supported by the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, and US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. Naltrexone, and other drugs used in medication-assisted treatment, are covered pharmacy benefits in Wisconsin's Medicaid Program and may be covered with a prior authorization in BadgerCare/BadgerCare Plus.

Thank you for the opportunity to speak with you today. I'd be happy to answer any questions you may have.

Answers to Frequently Asked Questions About Naltrexone Treatment for Alcoholism *

1. What is naltrexone?

Naltrexone is a medication that blocks the effects of drugs known as opioids (a class that includes morphine, heroin or codeine). It competes with these drugs for opioid receptors in the brain. It was originally used to treat dependence on opioid drugs but has recently been approved by the FDA as treatment for alcoholism. In clinical trials evaluating the effectiveness of naltrexone, patients who received naltrexone were twice as successful in remaining abstinent and in avoiding relapse as patients who received placebo-an inactive pill.

2. Why does naltrexone help for alcoholism?

While the precise mechanism of action for naltrexone's effect is unknown, reports from successfully treated patients suggest three kinds of effects. First, naltrexone can reduce craving, which is the urge or desire to drink. Second, naltrexone helps patients remain abstinent. Third, naltrexone can interfere with the tendency to want to drink more if a recovering patient slips and has a drink.

3. Does this mean that naltrexone will "sober me up" if I drink?

No, naltrexone does not reduce the effects of alcohol that impair coordination and judgment.

4. If I take naltrexone, does it mean that I don't need other treatment for alcoholism?

No, naltrexone is only one component of a program of treatment for alcoholism including counseling, help with associated psychological and social problems and participation in self help groups. In both studies where naltrexone was shown to be effective, it was combined with treatment from professional psychotherapists.

5. How long does naltrexone take to work?

Naltrexone's effect on blocking opioids occurs shortly after taking the first dose. Findings ton date suggest that the effects of naltrexone in helping patients remain abstinent and avoid relapse to alcohol use also occur early.

6. Are there some people who should not take naltrexone?

Naltrexone should not be used with pregnant women, individuals with severe liver or kidney damage or with patients who cannot achieve abstinence for at least 5 days prior to initiating medications. Also, people who are dependent on opioid drugs like heroin or morphine must stop their drug use at least 7 days prior to starting naltrexone.

7. What does it feel like to be on naltrexone?
Aside from side effects, which are usually short-lived and mild, patients usually report that they are largely unaware of being on medications. Naltrexone usually has no psychological effects and patients don't feel either "high" or "down" while they are on naltrexone. It is not addicting. While it does seem to reduce alcohol craving, it does not interfere with the experience of other types of pleasure.

8. What are the side effects of naltrexone?

In the largest study, the most common side effect of naltrexone affected only a small minority of people and included the following: nausea (10%), headache (7%), dizziness (4%), fatigue (4%), insomnia (3%),

anxiety (2%), and sleepiness (2%). These side effects were usually mild and of short duration. As treatment for alcoholism, naltrexone side effects, predominantly nausea, have been se vere enough to discontinue the medication in 5-10% of the patients starting it. For most other patients side effects are mild or of brief duration. One serious possibility is that naltrexone can have toxic effects on the liver. Blood tests of liver function are performed prior to the onset of treatment and periodically during treatment to determine whether naltrexone should be started and whether it should be discontinued if the relatively rare side effect of liver toxicity is taking place.

9. Do I need to get blood tests while I'm on naltrexone? How often?

To ensure that naltrexone treatment is safe, blood tests should be obtained prior to initial treatment. Following that, retesting generally occurs at monthly intervals for the first three months, with less frequent testing after that point. More frequent testing may be requested depending on the health of your liver prior to beginning treatment. Blood tests are needed to make sure that liver function is adequate prior to taking naltrexone and to evaluate whether naltrexone is having adverse effects on the liver.

10. Can I take other medications with naltrexone?

The major active effect of naltrexone is on opioid drugs, which is one class of drugs used primarily to treat pain but is also found in some prescription cough preparations. Naltrexone will block the effect of normal doses of this type of drug. There are many non-narcotic pain relievers that can be used effectively while you are on naltrexone. Otherwise, naltrexone is likely to have little impact on other medications patients commonly use such as antibiotics, non-opioid analgesics (e.g., aspirin, acetaminophen, ibuprofen), and allergy medications. You should inform your physician of whatever medication you are currently taking so that possible interactions can be evaluated. Because naltrexone is broken down by the liver, other medications that can affect liver function may affect the dose of naltrexone.

11. Will I get sick if I drink while on naltrexone?

No. Naltrexone may reduce the feeling of intoxication and the desire to drink more, but it will not cause a severe physical response to drinking.

12. Will I get sick if I stop naltrexone suddenly?

Naltrexone does not cause physical dependence and it can be stopped at any time without withdrawal symptoms. In addition, available findings regarding cessation do not show a "rebound" effect to resume alcohol use when naltrexone is discontinued.

13. What should I do if I need an operation or pain medication?

You should carry a card explaining that you are on naltrexone and that also instructs physicians on pain management. Many pain medications that are not opioids are available for use. If you are going to have elective surgery, naltrexone should be discontinued at least 72 hours beforehand.

14. What is the relationship of naltrexone to AA?

There is no contradiction between participation in AA and taking naltrexone. Naltrexone is not addictive and does not produce any "high" or pleasant effects. It can contribute to achievement of an abstinence goal by reducing the craving or compulsion to drink, particularly during early phases of recovery. It is most likely to be effective when the patient's goal is to stop drinking altogether.

15. How long should I stay on naltrexone?

If naltrexone is tolerated and the patient is successful in reducing or stopping drinking, the recommended initial course of treatment is 3 months. At that time the patient and clinical staff should evaluate the need for further treatment on the basis of degree of improvement, degree of continued concerns about relapse and level of improvement in areas of functioning other than alcohol use.

**From the Pamphlet, "Guidelines for the Use of Naltrexone in the Treatment of Alcoholism" by Bruce J. Rounsville, M.D., Stephanie O'Malley, Ph.D., and Patrick O'Connor, M.D. – The APT Foundation, 904 Howard Avenue, New Haven, CT 06519*